#108501

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SUBJECT: Tolerance for Prowl N-(1ethylpropyl)-3, 4,-dimethyl-2, 6-dinitrobenzeneamine on Sunflowers (0.1 ppm)

DATE: February 18, 1977

FROM: Toxicology Branch

TO: Special Registration Section
Ms. Libby Zink

Pesticide Petition 7G1896
Petitioner: American Cyanamid Company

Conclusion:

1. Establish temporary tolerance.

2. Inform petitioner that a cataract study is needed for this compound.

3. Grant EUP.

Substance identification -
See title, CL 92553, AC 92553.

Referenced Petition:

4G1451, 5F1556

Review:

No new toxicology studies were submitted, prior reviews, see above petitions and memo of February 22, 1975. The toxicity studies submitted on this chemical and the 4E Formulation are summarized as follows:

Acute tests (technical)

oral LD_{50}rat	1.05 g/kg female	1.25 g/kg male
oral LD_{50}mouse	1.34 g/kg female	1.62 g/kg male
dermal LD_{50}rabbit	>5 g/kg	
skin irritation (rabbit)	not irritating	
eye irritation (rabbit)	not irritating	

Acute tests 4E formulation

oral LD_{50}rats	3.38 g/kg
dermal LD_{50}rabbit	>2 ml/kg (judged from subacute study)
skin irritation rabbit	moderate to severe irritant
eye irritation rabbit	very slight and reversible irritation

No dead animals opacity - see review (8/12/77 - Spencer)

EPA Form 1320-6 (Rev. 6-72)

Subqcute and long-term tests

21 day dermal (rabbit)	No effect for 1g/kg/day technical, slight to moderate erythema and edema for 2 ml/kg/day of 4E formulation
90-day rat feeding study	NEL 500 ppm
90-day dog feeding study	NEL 62.5 mg/kg (2500 ppm).
2-year rat feeding study	NEL 500 ppm, no oncogenic effects
18 months mouse study	NEL 500 ppm, no oncogenic effects
3 generation study rats	NEL 500 ppm
Teratology (rat)	No effect at 1g/kg/day
Dominantlethal study	No effect at 2500 ppm (highest dose)
Effects on male mammary glands	No effect at 5000 ppm (highest dose)

The ADI for man can be calculated based on long-term studies and is 15 mg/day for a 60 kg man. All tolerances which are established under 180.361 and all pending tolerances are at the 0.1 ppm level, the ADI thus is not exceeded.

Reto Engler, Ph.D.

E/a CEI 2/22/77